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Non-intrusive Patient Simulator for Medical Ventilator Software Verification

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Dedicated to my beloved parents,

for their constant love and support

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Abstract

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Testing distributed real-time systems has been pervasively proven a challenging task within numerous industries. When the real-time nature of a system is combined with safety critical medical systems, having a reliable test system is of major importance. However, the hardware dependency makes it very difficult to test medical ventilator software system in failure mode and requires manual manoeuvres, prohibiting test automation for numerous features.

To achieve entire test automation, an embedded patient simulator is proposed in this thesis. A simulator that simulates a human lung runs separately on embedded platform and interacts with the ventilator so that all the hardware dependencies could be removed. It is of non-intrusive implementation and all the real-time properties of the ventilator software system could be tested on target. Software-implemented fault injection is realized as well, which is a significant step to fault-tolerance testing for safety critical system.

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Chapter 1

Introduction

This thesis project is conducted at Maquet Critical Care AB, Getinge Group. Getinge Group is a world leading medical technology company with operations in the areas of surgery, intensive care, infection control, care ergonomics and wound care. The Group is now organised in three business areas: Medical Systems, Extended Care and Infection Controls. Maquet Critical Care AB is one of the subsidiaries with focus on intensive care. They develop, manufacture and market medical devices, among which are the medical ventilators.

Today, medical ventilator is a commonly used medical device, mostly equipped in the Intensive Care Unit(ICU). It is imperative in many forms of Acute Respiratory Failure (ARF), which is associated with mortality rates of between 40% and 65% [1, 2]. As Esteban and his team reported in a prospective study including 15757 patients from 20 countries, 33% (5183) of the admitted patients received mechanical ventilation for a mean (SD) duration of 5.9 (7.2) days, while the mean (SD) length of stay in ICU was 11.2(13.7) days.[3]

As the prevalence of the mechanical ventilation, numerous international standards, such as[4, 5], have been established to regulate the safe design and maintenance of medical ventilators. Medical devices should be fault-tolerant to protect patients from unacceptable risks. Risk management and robustness verification has consumed tremendous time and costs during the ventilator development.

Maquet ventilator system is a distributed real-time systems, which has been repeatedly proven challenging to test in diverse industries. When the real-time nature of a system is combined with safety critical medical systems, having a reliable test system, is of major importance. This is to verify the software as well as ease and accelerate the development process. The correctness of a real-time system does not depend only on

the output validity, but also on meeting the timing requirements. Therefore the testing system shall also be able to verify the temporal validity of the system.

Maquet Critical Care produces ventilation systems with an advanced real-time computer platform consisting of three separate subsystems. During development, subsystems are built and tested on Linux hot computers. This testing methodology does not address real-time issues. Real-time properties are always tested on target and this is highly dependent on the gas chain. The gas chain, from the software perspective, is sensed as a number of pressure, temperature and gas flow measurements sampled by FPGA. The same Integrated Circuit(IC) is also used to control and regulates the valves and other actuators on the system. The hardware dependency makes it very difficult to inject faults and it requires manual manoeuvres, prohibiting test automation for numerous features.

To realize automated software testing on target, a non-intrusive patient simulator is proposed in this thesis. The patient simulator tries to simulate a real human lung model and the gas chain of the ventilator. It works on a standalone embedded platform and is connected to the ventilator via an SPI bus. All the sensors would be disconnected from the ventilator and they are replaced by the simulated data which is exported from the patient simulator. Meanwhile, simulator takes the actuator reference signals as input signals for simulation step. Therefore, the hardware dependencies are removed from the software system.

To test software reliability and fault-tolerance, fault injection is realised in a software way. It works in server/slave mode and hardware fault could be simulated and injected from the host side.

With no doubt, this will be a significant breakthrough for verification methodologies at Maquet.

Chapter 2

Background

2.1 Respiratory Physiology

The metabolism of human beings is dependent on a continuous supply of oxygen (O_2) and the removal of carbon dioxide(CO_2) from the human body. An extraordinary anatomic arrangement of functional units(the alveoli) bordered epithelium and endothlium creates the interfaces for gas exchange between blood and surroundings. The gas transport to and from the cells is accomplished by the cooperation of two systems, the respiratory system and the circulation system. Respiratory systems undertake the gas exchange with the surroundings and oxygenate the blood, while the circulation systems transport oxygen from the lungs to the cells.

Thus we could separate the respiration into two phases, the internal one and external one. The external respiration is the gas exchange between the alveoli and the blood, controlled by the respiration system, and the internal one is the gas exchange between blood and cells, which is accomplished by the circulation system. Further on, when talking about respiration, only the external one in intended.

Functionally, the lung could be divided into two regions: a conducting zone comprised of airways and a respiratory zone containing smaller airways with alveoli. The chest wall consists of the ribcage, abdomen and diaphragm.[6]

The diaphragm is the primary muscle of inspiration. During spontaneous inhalation, air moves into the lung due to adomeshaped structure that forces abdominal contents downward and forward with contraction resulting in an increase in volume of the thorax. This results in a pressure drop in the pleurae which expands and lungs are stretched together. As the pressure falls, air moves into the conducting zone. Contraction of

external intercostal muscles and accessory muscles would further expand the thoracic volume, especially during forced inspiration, as when taking a deep breath.

In general, expiration is a passive process. During expiration the respiratory system returns toward its resting volume and the lung relaxes and retakes its original shape because of its natural elasticity and therefore carbon dioxide could be removed from human body. However active or forced exhalation can be achieved by abdominal and the internal intercostal muscles.

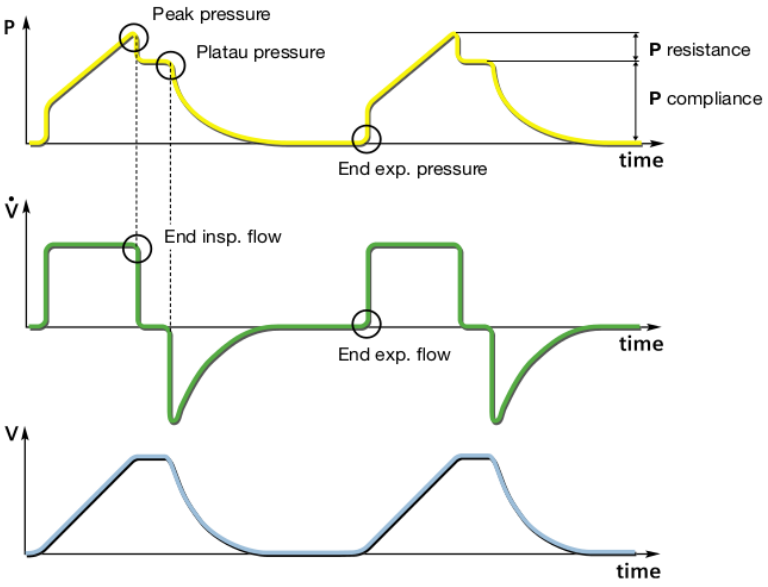
2.2 Mechanical Ventilation

According to the extent of patients' dependence on the mechanical ventilation support, we classify breathing into three types, respectively the controlled breathing, assisted breathing and spontaneous breathing. As the name implies, spontaneous breathing means that patients could breath spontaneously and need no mechanical ventilation support, just as healthy adults do. Assisted breathing helps the patients' own respiratory attempts while during controlled breath respiration is only controlled by the ventilator.

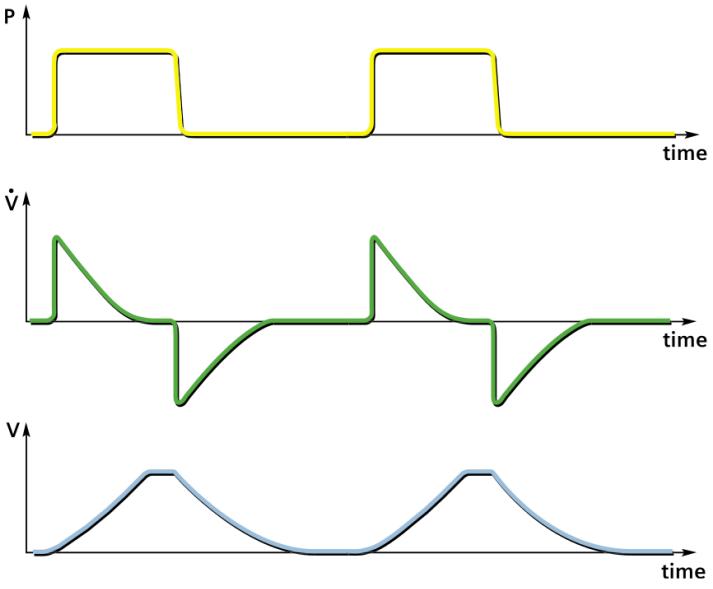
Mechanical ventilation is commenced for the failure to ventilate or to oxygenate. It is required when a patient is unable to achieve adequate ventilation and thereby gas exchange. Mechanical ventilation can help relieve respiratory distress and improve pulmonary gas exchange. None of the ventilation mode can cure the disease process. However, it supports ventilation till you address the reversible primary problem.

Only two ways exist to mechanically ventilate a patient, using positive pressure or negative pressure. Some of the earliest ventilators were negative pressure chambers (iron lungs). In the mid 1950s, iron lungs were presented to manually ventilate paralysis victims until restoration of neuromuscular activity occurred. Iron lungs mimicked the chest cage's activity in generating minute ventilation, but were of little value in diseases characterized by failure to oxygenate. The machines were bulky, expensive and somewhat unhygienic.

Almost all modern ventilators employ intermittent positive pressure ventilation, which means implement lung inflation by applying positive pressure to the airways. This makes sense as the chest is a negative pressure ventilator. The first positive pressure ventilators were pressure controlled. Volume controlled ventilators became ubiquitous in the 1960s as this mechanism was perceived to be more reliable at delivering minute ventilation, and thus normalizing blood gases.



(a) Volume Targeted



(b) Pressure Targeted

FIGURE 2.1: Volume and Pressure Targeted Ventilation

Today, the prevailing mechanical ventilation modes could be categories as volume targeted control and pressure targeted control. Figure 2.1 is the comparison between volume targeted and pressure targeted ventilation. In pressure targeted ventilation, gas is supplied into the lung until a present airway pressure limit is reached. The oxygen delivered varies with changing of the patients' lung and airway characteristics, compliance and resistance, which we would explain in details in Chapter 5. In volume targeted ventilation, gas flows into the patients lung until a preset volume of gas is delivered, even if this entails a very high airway pressure.

Technology has played a large part in the development of modern ventilators. Physicians are now demanding more control over gas flow than before - hence the development of active exhalation valves, dynamic inspiration valves, rise time control, automatic tube compensation and, of course, waveform analysis. Modern ventilators deliver enhanced patient interactivity using better triggering sensors, and more comfortable spontaneous breathing.

2.3 Maquet Ventilator

Maquet is a global leader in providing medical ventilator systems intended for treating and monitoring patients ranging from neonates to adults with respiratory failure or respiratory insufficiency. It meets the requirements of the most medically challenging patients, even exceeds the expectations of their medical professionals.

Here we would profile the Maquet ventilator system. Appendix A gives the main blocks diagram of Maquet SERVO-i ventilator.[7] Roughly speaking, Maquet ventilator system consists of three components[7, 8]:

- User Control Interface – for setting ventilation modes, displaying patient data and indicating alarms and warnings
- Gas chain – Mix gases, deliver and exchange gas. It consists of the complicated electronics and mechanics in the ventilator. Abundant sensors and actuators are placed in the gas chain, which makes the mechanical ventilation observable and controllable.
- Software System – control and regulate the mechanical ventilation at each breath moment.

Among the above components, the ventilator gas chain is directly connected with the patients' respiratory system , which means gas chain would supply oxygen to the patients

FIGURE 2.2: MAQUET SERVO Ventilator

and remove carbon dioxide from the human body. Therefore, we would mainly cast light upon the gas chain internal structure in this section to give the basic idea of how a medical ventilator works to support patients' respiratory.

Generally speaking, the gas chain could be divided into two sections: the inspiratory section and expiratory section. Figure 2.3 highlights the significant sensors and actuators/valves in the gas chain. Above the dash line is the inspiratory section while the expiratory section is under the dash line.

The inspiratory section conveys the breathing gas from the gas inlets for air and O_2 supply to the patient respiratory system. It comprises the following main functions:

- *Gas Module:* The air and O_2 gas modules regulates the inspiratory gas flow and gas mixture. It includes measuring devices such as inspiratory temperature sensor, supply gas transducer and flow transducer and so on.
- *O_2 Cell/Sensor:* The O_2 Cell gives an output voltage proportional to the partial pressure of oxygen inside the inspiratory pipe. The O_2 Sensor, which is a measuring device for the inspired oxygen concentration, is an alternative to the O_2 Cell. It uses ultrasound technique with two ultrasonic transducers/receivers.
- *Temperature Sensor:* A temperature sensor is integrated into the connector to measure the gas temperature inside the Inspiratory Section.

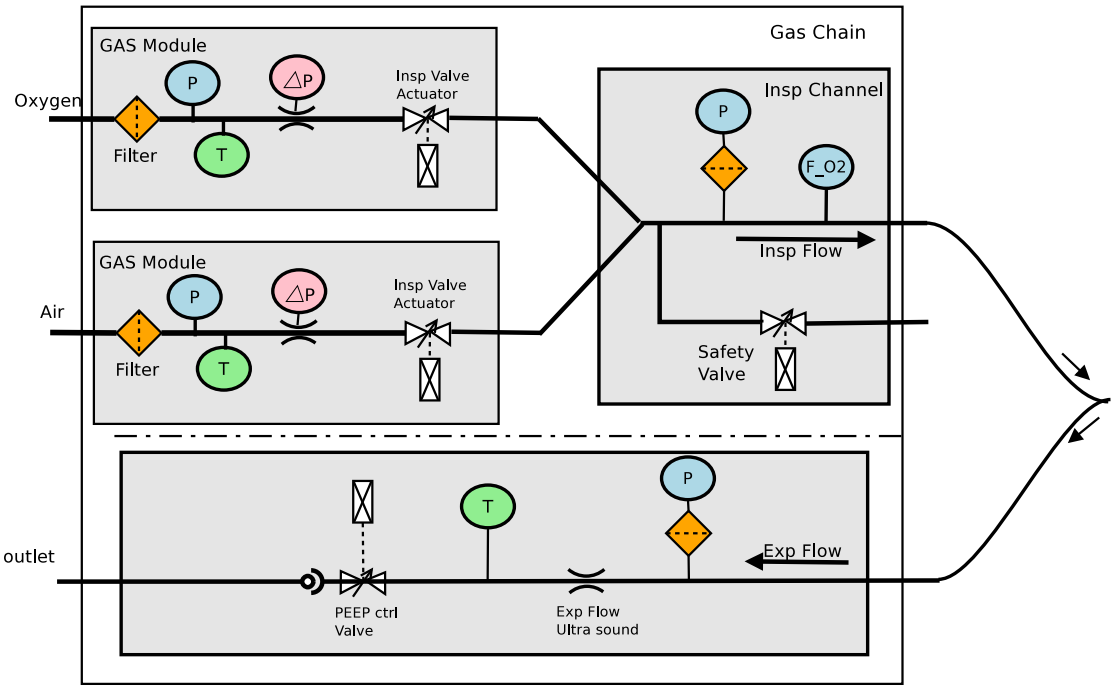


FIGURE 2.3: MAQUET Ventilator Gas Chain
[P: Pressure Sensor; T: Temperature Sensor; ΔP: Gas Flow; F_O2: Oxygen Concentration Sensor]

- *Safety Valve:* The safety valve is designed to protect patients from high inspiratory pressure. It's under control of software systems.

Expiratory section conveys the expiratory gas from the patient respiratory system to the expiratory outlet. It comprises:

1. *Flowmeter:* Measurement of expiratory flow
2. *Pressure Sensor:* Measurement of expiratory pressure
3. *Outlet Valve:* Control for the regulation of expiratory gas

During inspiratory phase, oxygen and fresh air would be supplied to the gas modules. The two gas modules regulate the inlet gas flow and mix the gas under the control of the software system. Due to the rise of pressure in the gas chain, the mixed fresh gas would be conveyed into patients' respiratory system. Hopefully, adequate oxygen should be delivered and oxygenate the blood. Worth mentioning, the safety valve in inspiratory section is designed for safety consideration. It protects the patients from excessive airway pressure.

When it is switched to expiration phase, the gas supply would be cut off and the outlet valve is open. As the natural elasticity, patients' lung relaxes and retakes its original shape so that it will pump out the exchanged air.

It is a periodic process. The gas chain is continuously sensed as a group of pressure, temperature, and gas flow, including the oxygen concentration, oxygen supply flow, air supply flow, oxygen supply pressure, air supply pressure, expiratory flow and expiratory pressure and so on. The difference between the actual measured value of a parameter and the preset or calculated value feedback to the actuators and results in the adjustment of gas delivery to achieve the target value.

Chapter 3

Platform Architecture

In the previous chapter, we have discussed the physical mechanism of Maquet Ventilator System. The gas chain is connected to patients' respiratory system directly. It is sensed as a number of pressure, temperature and gas flow measurements so that appropriate oxygen is delivered and meanwhile patients feel comfortable.

All the control and regulation is implemented by the software system. Here we could give emphasis on the system architecture and software subsystems.

3.1 System Architecture

3.1.1 Software System Overview

Maquet Ventilator software system is a distributed real-time system. A bunch of PC boards are carried on the ventilator. Each PC board has its own CPU to coordinate all the on-board electronics and all the boards can communicate with each other and keep synchronized. In this way, the PC boards carry diverse functions and play different roles in the entire system. They cooperate with each other and meanwhile get rid of interferences from each other.

Figure 3.1 profiles the architecture of a Maquet ventilator. As we can see, the ventilator system consists of three primary PC boards: *Breathing subsystem*, *Monitoring subsystem*, *Panel subsystem*. Appendix A gives a more detailed system main block diagram. Each individual card is an embedded Linux system with its own ARM processor, memory and peripheral I/O interfaces. Specific software subsystems are installed on the corresponding embedded system.

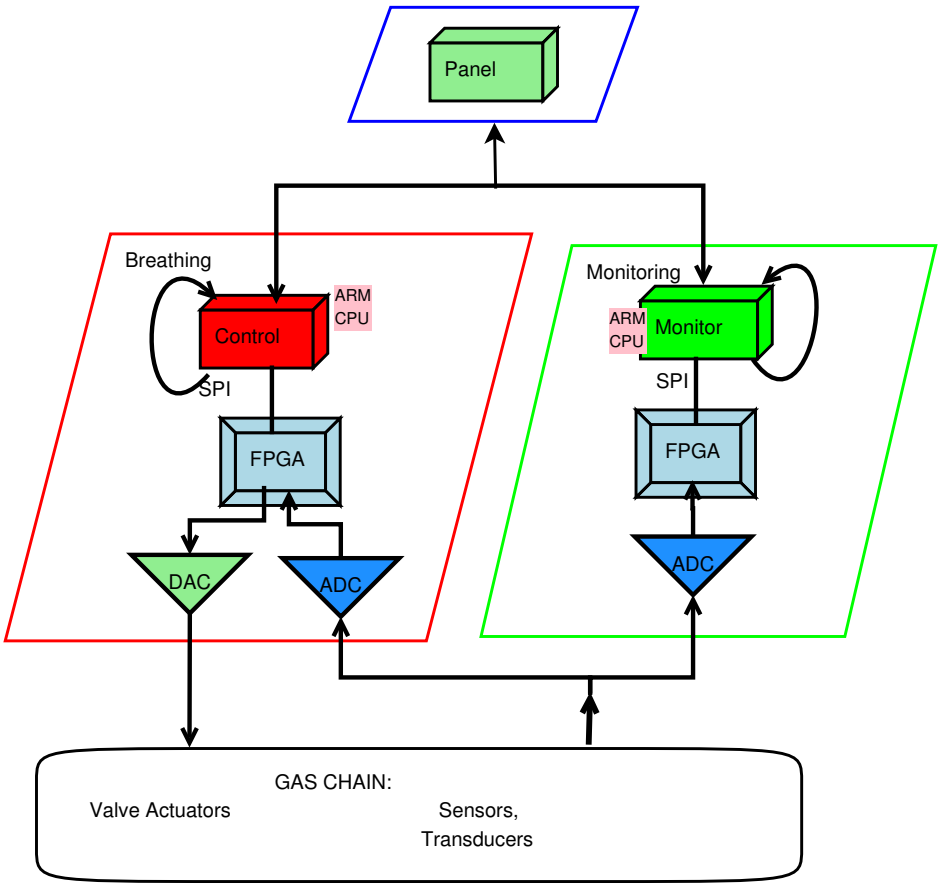


FIGURE 3.1: Maquet Ventilator System Architecture

Coulouris et al.[9] identify plenty of advantages of distributed system development. Combined with the Maquet ventilator system, we could summarize as the following:

1. *Resource Sharing* A distributed system allows the sharing of hardware resources. The straightforward example here are the sensors shared by breathing and monitoring subsystems.

2. *Parallel Computing* In distributed systems, several processes could operate at the same time on separate computers on the network. Different subsystems run on separate computers.

3. *Fault tolerance* The availability of several computers and the potential for replicating information means that distributed systems can be tolerant of some hardware and software failures.

3.1.2 Breathing Subsystem

The *Breathing Subsystem* controls the ventilation system, which is the ventilation control and regulation, inspiratory channel and expiratory channel. Electronics including microprocessor handle of [7]:

1. Respiratory timing pattern including respiratory ratio as well as distribution of the duration for inspiration, pause time and expiration time according to the front settings.
2. Regulation of inspiratory flow and pressure during inspiration time. The desired total inspiratory flow value according to front panel settings is used to generate the flow reference signals for both oxygen and air supply flows. The level relation between these two flow reference signals depends on the desired O_2 concentration according to front panel setting. These two reference signals are used for the control of its respective Gas Module.
3. Regulation of expiratory flow.

If we model the medical ventilator as an embedded control system, the breathing subsystem is the controller of the system. The breathing subsystem keeps observing gas chain characteristics, including all the breathing parameters. The difference between the actual measured value and the target value would be taken as input of the breathing subsystem. Besides, the breathing subsystem will listen on some system logic signals as well, taking the power condition and alarm buzzer as examples. After some advanced calculation, which depends on the front-panel setting mode and arguments, breathing subsystem would export some actuator reference signals to regulate the inlet and outlet flow and pressure.

The input signal set consists of 24 analogue breathing parameters and 24 system logic signals in total. Meanwhile, there are 4 analogue reference signals and 24 logic signals which are exported to gas chain electronics. Table 3.1 lists some of the input signals that we are interested in.

As known to all, micro-controller could only process digital data while the sensors output some analogue voltage. And it would be time-consuming for the micro-controller to poll all the ADC channels. This explains the existence of the FPGA between the gas chain and the microprocessors in Figure 3.1. FPGA is presented to bridge analogue and digital world. FPGA, rather than the CPU directly, would poll the *ADC(analogue-to-digital converter)* channels periodically at 2000 Hz. All the ADC siganls would be stored on a block RAM. At the same time, FPGA applies the actuator reference value to the

Signal Name	Signal Type	Subsystem(Mon/Bre/Both)
expiratory Pressure	ADC signal	Both
Oxygen Flow	ADC signal	Both
Barometer Pressure	ADC signal	Both
Safety Valve	Digital Input	Both
Buzzer	Digital Input	Mon
Disable Valve	Digital Input	Mon

TABLE 3.1: Sensors and Actuators

valves through the *DAC(digital-to-analogue converter)* channels. On the other side, the FPGA block RAM would be synchronised with the CPU on the SPI bus. Instead of sampling the gas chain directly, CPU would communicate with FPGA and read data from the block RAM which is very efficient. And it is the same story for the monitoring subsystem.

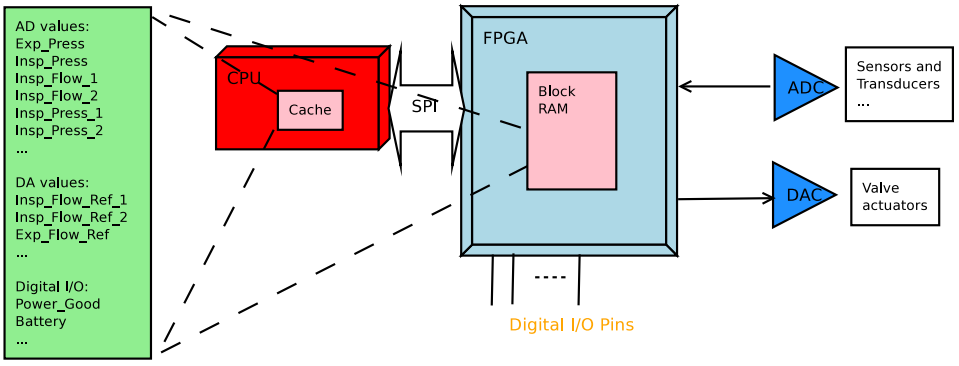


FIGURE 3.2: Sensor an I/O Data Acknowledge

3.1.3 Monitoring Subsystem

As discussed, medical ventilators are highly safety critical system. Even with the most careful fault avoidance development, faults will eventually occur and result in a system failure. Fault-tolerance techniques is mandatory in the medical ventilator development. Fault-tolerant system development should be based on a dependable process. A dependable system architecture is also essential for dependability. Ian Sommerville[10] explains that such a system architecture should be designed to include **redundant** components and mechanisms that allow control to be switched from one component to another.

Laprie[11] classified redundancy into four types: hardware redundancy, time redundancy, information redundancy and software redundancy. The simplest realization could be a replicated servers, where two or more servers carry out the same task. Replicated servers provide redundancy but not usually diversity. **Diversity** means that the redudant

subsystems are of different types, different functionality, thus increaing the chances that they will not fail in exactly the same fault.

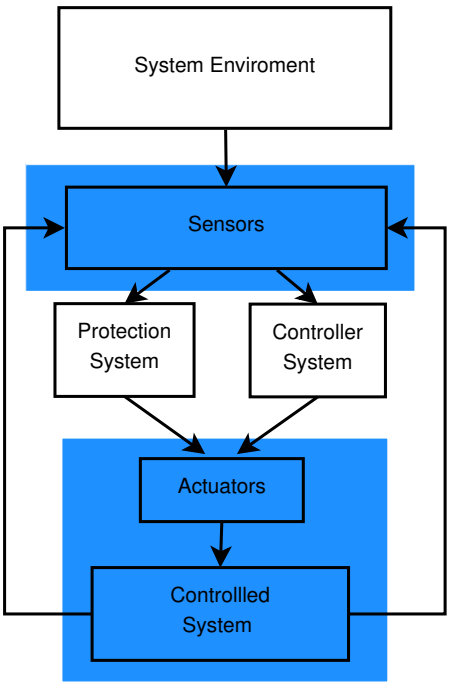


FIGURE 3.3: Protection System Architecture

Sommerville [10] summarizes a protection system with both redundancy and diversity. Figure 3.3 illustrates the relationship between the protection system and the controller system. Both the controlled system and environment are monitored by the protection system to provide improved reliability. Maquet Ventilator adopts such a dependable system architecture and the *Monitoring Subsystem* is the protection subsystem here. The protection subsystem only includes the critical functionality that is required to move the system from a potentially unsafe state to a safe state.

As the name implies, the monitoring subsystem controls all monitoring and alarm functions in the system, including trends of measured values. Events, such as alarms and change of system settings would be logged. If some problems detected, it issues alarms and leads the system to a safe state, which means to recover from the failure or just to shut down and stop service. To guarantee the patient one hundred percent safe, it activates pressure reducing mechanisms, including activation of the safety valve, in case of excessive breathing system pressure.

All alarms are conveyed and displayed on the front panel and the alarm sound is also generated. In case of malfunction in the loudspeaker located on panel, a back-up sound generating device (buzzer) on Monitoring PC board will be activated automatically. This buzzer is monitored by a microphone at start-up and during the pre-use check.

The buzzer on monitoring card generates the alarm signal in case of +5 V or +3.3 V power failure. The buzzer and +5/+3.3 V failure logic is powered by back-up capacitors in case of power failure.

3.1.4 Panel Subsystem

The panel subsystem implements all the user ventilator interaction, as well as software updating to all subsystems via the PC card interface. User could configure patient information and technical parameters on the touch screen.

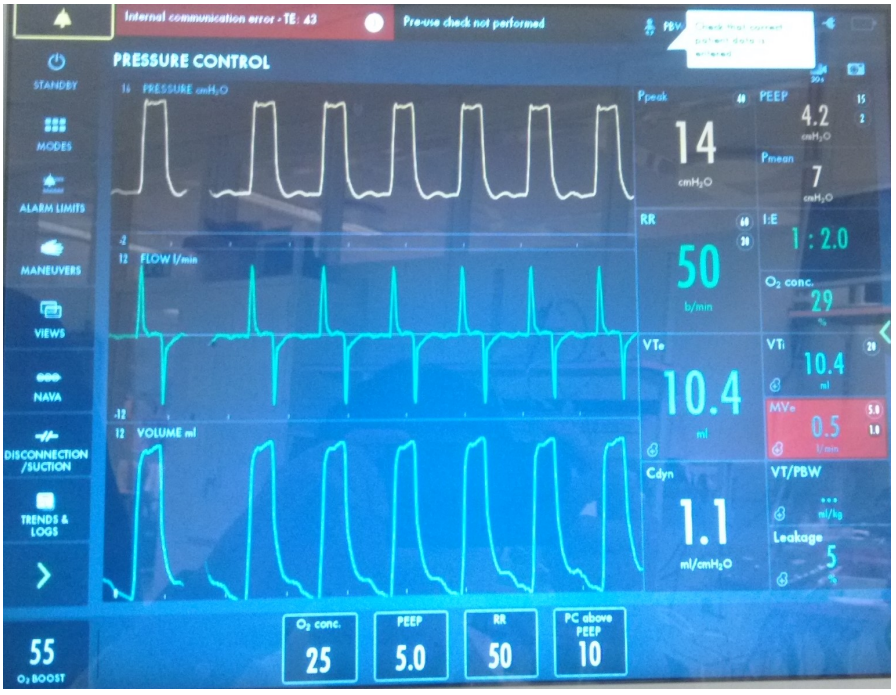


FIGURE 3.4: Ventilate an Infant

What's more important, real time breathing parameters could also be displayed on the panel. During ventilation, measured or calculated values of breathing parameters are displayed. Besides the breathing parameters, some color-coded waveforms will be shown on the user interface screen as well. By default, they are:

- *Pressure vs Time*
- *Flow vs Time*
- *Volume vs Time*

Thus, the user could have a straightforward knowledge of the patient's respiratory condition. Foremost, the warning and alarms will be displayed on the user interface screen.

3.2 Interaction and Communication

Distributed systems are more complex than systems that run on a single processor. There are several important issues that have to be considered in distributed systems engineering. One of the most significant things is *Communication and Interaction*. It includes the inter-subsystem communication and the inner communication between different components in a single subsystem.

Today the principal techniques applied in Maquet ventilator are Serial Peripheral Interface(**SPI**) and Google Protocol Buffer(**GPB**).

3.2.1 Serial Peripheral Interface

As illustrated in Section 3.1.2, SPI bus is designed to exchange data between CPU and FPGA block RAM in both breathing and monitoring subsystems. It is also utilized between breathing and monitoring subsystems. The SPI bus is short for *Serial Peripheral Interface*. It's a four-wire serial bus and devices work in master/slave mode, where the bus master always initiate the message transaction. The slaves are allowed by individual chip select lines.

3.2.2 Google Protocol Buffer

Google protocol buffer is a Language neutral, platform neutral and extensible way of serializing structured data. Protocol buffers are developed, used and well documented by Google[12]. It is flexible, efficient and automated, like XML, but smaller, faster and simpler. Another advantage of protocol buffer is that it supports multiple languages, Java, C++ and python as well. Protocol buffers are now Google's lingua franca for data. They're used both in Remote Procedure Call(RPC) systems and for persistent storage of data in a variety of storage systems.

You can specify the your own data structure and details of the information being serialized. Each protocol buffer message is a small logical record of information, containing a series of name-value pairs. Then you can use special generated source code to easily write and read your structured data to and from a variety of data streams and using a variety of languages. There are three steps to define a nice tidy protocol buffer message.

1. Specify Field Types Data in messages is hierarchically structured. Each message has one or more uniquely numbered fields. Each field has its name and value. Google protocol buffer supports various value types. It can be numbers, no matter integer

or floating point. It can be boolean, strings and raw bytes. What's more, you can even encapsulate other protocol buffer message types, which makes it more flexible and powerful.

2. Assign Unique Tag As mentioned, each field in the message definition has a unique numbered tag. These tags are used to identify your fields in the message binary format, and should not be changed once your message type is in use. Note that tags with values in the range 1 through 15 take one byte to encode, including the identifying number and the field's type. Tags in the range 16 through 2047 take two bytes. So you should reserve the tags 1 through 15 for very frequently occurring message elements. Remember to leave some room for frequently occurring elements that might be added in the future.

3. Specify Field Rules All the message field should be specified as one of the following[12]:

- **required** a well-formed message must have exactly one of this field.
- **optional** a well-formed message can have zero or one of this field (but not more than one).
- **repeated** this field can be repeated any number of times (including zero) in a well-formed message. The order of the repeated values will be preserved.

Today, protocol buffers are applied in Maquet ventilator systems as well. Messages goes through Ethernet and synchronise different subsystems.

Chapter 4

Software Testing

As a highly safety critical system, it is essential that the applied software is trustworthy. The European Standard EN 60601-1:2006[13] has define the basic safety requirement as freedom from unacceptable risk directly caused by physical hazards when medical electrical equipment is used under **normal condition** and **single fault condition**. The software should be available to provide service when required and should operate correctly and without undesired **risks** and **hazards**[5].

4.1 Dependability and Fault tolerance

The term **dependability** was proposed by Laprie in 1985[11] to cover the related system attributes of **availability** and **reliability**. As Laprie delivered in his article, achieving a dependable computing system calls for the combined utilization of **fault-avoidance**, **fault-tolerance**, **error-removal**, and **error-forecasting**, where fault-avoidance and fault-tolerance may be seen as constituting dependability procurement. Fault-tolerance tightly relates to safety critical systems that should include facilities to handle with abnormal or anomalous conditions.

All the software **system** is designed to provide specified **service**. System **dependability** is the quality of the delivered **service** such that reliance can justifiably be placed on this service. If the system stops delivering the intended service, we call this a **failure**. We call the cause of failures **fault**. A fault causes an **error** in the internal state of the system and the error eventually results in the system **failure**.

Faults can be hardware faults or software faults. Component defect is, of course, a hardware fault. For example, a pressure sensor in the gas chain fails to measure the pressure correctly. Hardware fault could also be a circuit break. Software fault is commonly

caused by code implementation. But a fault can also be the external environment and disturbances like electromagnetic interference and operator mistakes.

The great diversity of faults makes the evaluation of a fault-tolerant system a definitely complex task. A great deal of studies, taking [14] as an example, have shown the prominent efficiency of the fault tolerance algorithms and mechanisms(FTAM's) on the dependability of abundant systems and architectures. Among the possible approaches such as proving or analytical modelling, **fault injection** is proven to be more attractive[15, 16, 17]

The main idea of **fault injection** is to speed up the occurrence of errors and failures. It is a method for testing the FTAM's with respect to their own specific faults, that they are expected to stand. [18] points out that fault injection addresses both error removal and error forecasting. With respect to the error removal objectives, fault injection is explicitly target at reducing, by verification, the presence of faults.

4.2 Formal Testing

Software testing is, as Myers defines in his book[19], *the process of executing a program with the intent of finding errors.* He divides testing before release into four main stages: module(unit) testing, integration testing, function testing and system testing. Figure 4.1 illustrates the testing cycle structured to model the development cycle.

Testing is first focused on the small individual components of the whole system, starting from module testing. After verifying the unit functional and interface specification, developers move to integration testing. As the name implies, integration testing works to expose the potential defects in the interaction of different modules. Progressively, larger groups of modules and components could be integrated and tested until systems. Both module and integration testing is conducted by developers during development phase.

As indicated in Figure 4.1, function testing is a process of attempting to dig out the deviations between the application and the external specification. An external specification is a precise description of the system's behaviour from the point view of the end user[19]. System testing is the most confusable process. It's not a process of testing the functions of the complete system. Instead, system testing is to compare the system to its original objectives. It's impossible if there is no set of written, measurable objectives for the system.

According to Myers' testing psychology[19],

A programmer should avoid attempting to test his or her own program.

Professional testers should take over the function and system testing instead of developers themselves. Usually, black-box testing is applied in this stage, because the internal logic and structure is unconcerned, which means it's input/output driven strartegy.

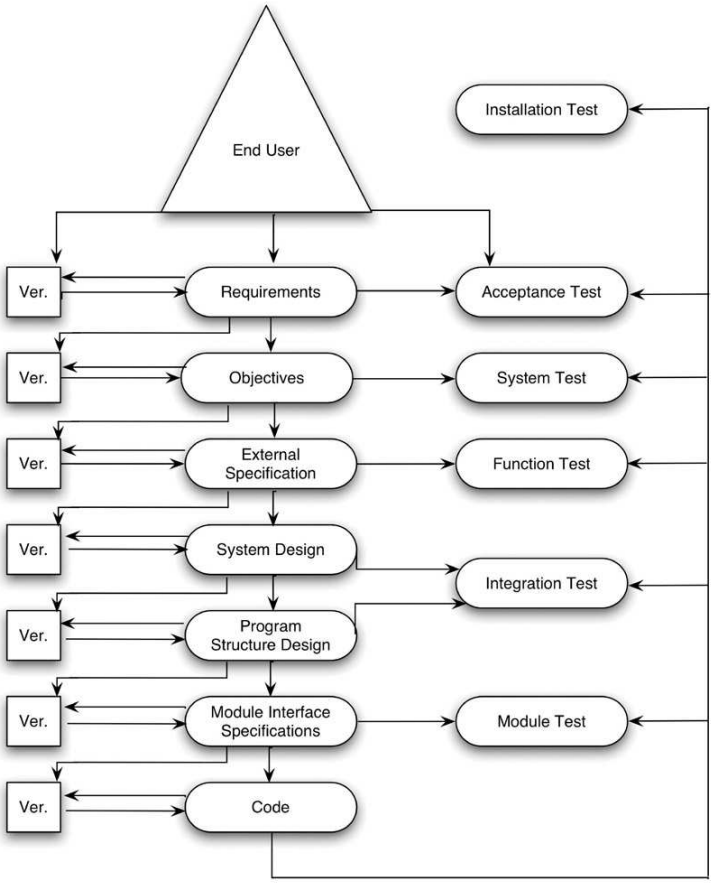


FIGURE 4.1: Development and Testing Processes

After an analysis 15 years of medical device recall data, Wallace points out in his study[20] that some specific test strategies might have been useful in detecting the potential faults before the system were released.

4.3 Challenges at Maquet

Today at Maquet, we could classify software testing into two categories: normal condition testing and failure mode testing. Normal condition means condition in which all means provided for protection against hazards are intact and operations according to the instructions for use. All the normal mode formal testing has already been automated and it's proven to be prominently efficient and trustworthy. However, it's still difficult to realize test automation under failure mode. Failure mode means that, for some uncertain faults, the system fails eventually. The software system should somehow recover from this abnormal and anomalous conditions and continue providing service or just shut down and stop service, which is safety critical system supposed to do.

Bluntly, tremendous manual testing are ongoing at Maquet in failure mode testing even today. We can first have a look at an example.

> A barometric pressure too low alarm shall be triggered if the measured barometric pressure is below (650±10) hPa(refer to Appendix B) and the barometer pressure used internally in the Monitoring Subsystem shall be limited to 650 hPa if a lower pressure is detected.

In this example, the error is the measured barometric pressure. This could result from the barometer defect or maybe because of circuit break. As illustrated in Section 3.1, software system read breathing parameters from the FPGA block RAM and FPGA polls the sensors and updates the block RAM at a high frequency. Which means that a single error would be flushed and overwritten in the next sampling cycle. The tight relation between the software system and the hardware components makes it much more challenging to inject the expected fault.

Before this thesis, manual job is mandatory to simulate and inject some barometer error. Testers have to apply a certain voltage that corresponds to the barometric pressure to the output pin of the barometer. This manual job counts up to 6 times in one single test case.(refer to AppendixB). This is an obvious obstacle to test automation.

The importance to test automation has been recognised long ago and is undisputed today. As Derk-Jan de Grood demonstrates in his book[21], manual testing is time consuming and cost consuming from business concern. What's worse, manual testing is error prone. Manual job is always potential fault source and the testing quality is not guaranteed. Rather than manual testing, automated testing has convinced to be much more promising. Alongside noticeable efficiency, automated testing has more controllability and reproducibility.

To summarize, the vast quantity of hardware dependencies becomes the bottleneck of automated software testing, especially in failure mode. Because manual fault injection can not replaced by automated implementation today.

Chapter 5

Patient Simulator

During development, subsystems are built and tested on Linux host computers. A simple simulation model for the ventilators gas-chain reads the actuator values from the CPU by using the shared memory paradigm and then calculates and returns the sensor values for each breath moment. Shared memory is utilized for Inter-Process Communication(IPC). Although the enormous contributions it makes, the simulator on host is far from enough to be used in system testing.

5.1 Physical Lung Model

5.1.1 Physical Characteristics

Many common diseases of the lung involve alterations in lung mechanics. Being able to characterize these alterations is thus of great importance. Most research involve the model based estimation of lung mechanics use two parameters to define how the lung behaves during respiration. They are the *compliance*, which is a measurement of the elasticity of the lung and thorax, and the *resistance*, which is the amount of pressure required to deliver a given flow of gas and is expressed in terms of a change in pressure divided by flow[22].

Compliance

The compliance is a measurement of the elasticity of the lung and the thorax. It's volume change as a function of transmural pressure change, or the slope of a volume pressure curve. In some other articles[23], *elastance* might be introduced as well, which is actually the reciprocal of compliance. Elastic recoil is the transmural pressure at a

special volume. Elastic attractions in the lung strive to discrease the volume of the lungs, while elastic attractions in the thorax tries to increase it. It's defined as:

$$C = \frac{\Delta V}{\Delta P_{alv}} \qquad [\frac{ml}{Pa}] \; or \; [\frac{m^5}{N}] \tag{5.1}$$

A small compliance relates to stiff lungs and a big value corresponds to flexible lungs. The compliance of the respiratory system is the compliance of the lung and the chest together, according to the equation 5.1:

$$\frac{1}{C_{tot}} = \frac{1}{C_{lung}} + \frac{1}{C_{thorax}} \tag{5.2}$$

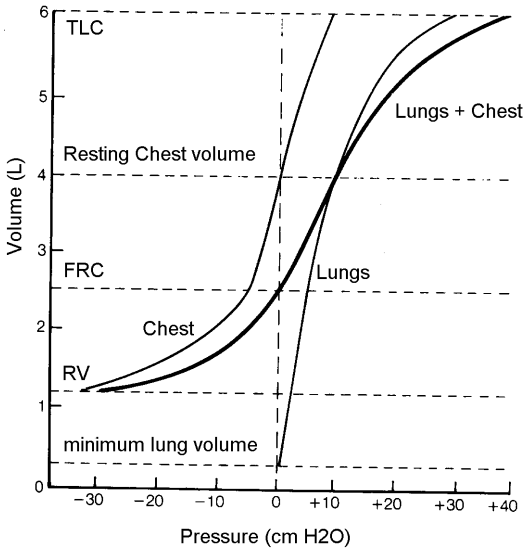


FIGURE 5.1: Compliance of the lung and chest[1]

As shown in Figure 5.1, it's the relationship between lung and chest compliance, which is the same as defined in the equation 5.1. Usually, the compliance of the lungs and the chest are approximately the same and a normal C_{tot} for adults is about 1 ml/Pa. Neonates have a compliance that is around 1/20 of adults, i.e. rough 0.05 ml/Pa,[24] or about 1 ml/cmH_2O per Kg of body weight.

One thing worth mentioning, as we know, compliance is the slope of the pressure-volume curve. But when plotting lung-chest wall volume vs. pressure, the curve is not the same during inflation and deflation. The dependence of a property on past history is termed hysteresis. As shown in Figure 5.2, the inflation and deflation characteristics of the lung are not identical. At a given volume the transmural pressure is higher during inflation and lower during deflation. The faster the volume is changed the greater the difference

[1] copyright@ http://www.acbrown.com/lung/Lectures/RsVntl/RsVntlCmpl.htm, available on February 2014

in pressure. This behavior is caused predominantly by the surface tension at the gas liquid interface.

Resistance

The *resistance* specifies the pressure needed to get a certain gas flow in the airways. As Ohm's law tells the relation between the pressure, ΔP, and the gas flow, $\dot{V}$:

$$R = \frac{\Delta P}{\dot{V}} \qquad [\frac{Pa \cdot s}{l}] \, or [\frac{N \cdot s}{m^5}] \tag{5.3}$$

Airway resistance depends on the properties of the given airways, as length, radius, breaching amend wall structure, but also on the air flow. In a given airway, the gas flow might be laminar or turbulent. Characteristics that promote turbulence include high flow rates, tubes that are not long and straight, and fluids with high density or low viscosity. During turbulent flow, the resistance is parabolic, and the supply pressure is proportional to the square of the flow, while during laminar flow, the resistance is proportional to the flow.

The total resistance of the whole respiratory system for adults is about 140-400 $Pa(l/s)$, but values up to 840 are normal. Neonates have a resistance that is about 15 times higher, i.e. about $6000Pa(l/s)$[24].

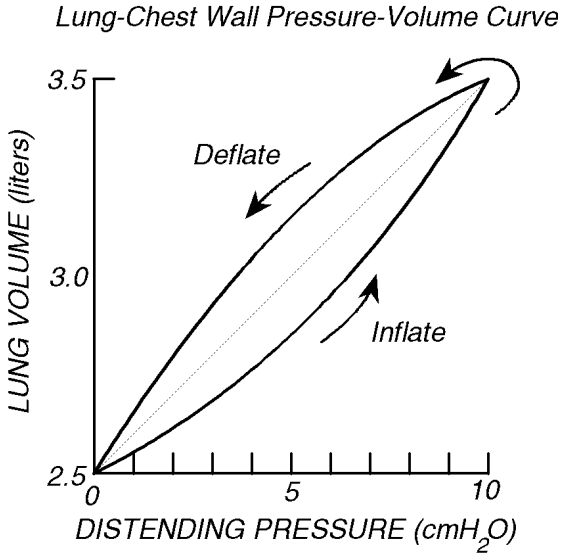


FIGURE 5.2: Hysteresis in the pressure vs. volume curse[2]

[2]copyright@ http://www.acbrown.com/lung/Lectures/RsVntl/RsVntlCmpl.htm, available on February 2014

5.1.2 Lung Model

The forces involved in respiration are mostly elastic and resistive. Depending on the utilization, different models are introduced to describe the human lung. However, a simple first order RC model is enough for most cases. The model consists of a serial arrangement of a resistance, representing the total airway resistance, R, and resistive tissue contributions and a compliance C, a measurement for the elasticity of the respiratory system.[25]

In the first order RC-model, the pressure in the lung is modeled as a linear equation of the sum the elastic properties of the lung and the resistance of the airway[26].

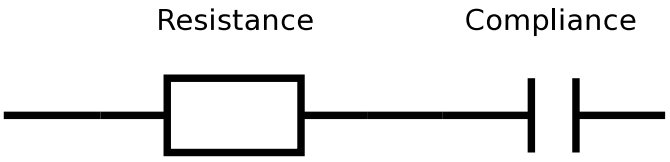


FIGURE 5.3: Simple RC Model

$$P \;=\; P_{el} \;+\; P_{res} \tag{5.4}$$

where, according to the compliance and resistance definition Equation 5.1, 5.3:

$$\left.\begin{aligned} P_{el} &= \frac{V}{C} \\ P_{res} &= \dot{V} \cdot R \end{aligned}\right\} \Rightarrow P = R \cdot \dot{V} \;+\; \frac{V}{C} \tag{5.5}$$

In the electrical circuit, the resistance could be compared to an electrical resistance and the compliance to a capacity, which would be charged and discharged for each respiratory cycle.

To have a better representation of the respiratory system, the simple RC-model could be extended to take two lungs into considerations, which would look as shown in the Figure 5.4. Usually the resistances R_L and R_R and the capacities C_R and C_L have the same value.

The RC model could be extended very easily. For instance, we could extend the model to a non-linear model to get a better lung behaviour description close to the reality. A non-linear model can take into consideration that the flow is no more laminar, but becomes turbulent at some flow speed.

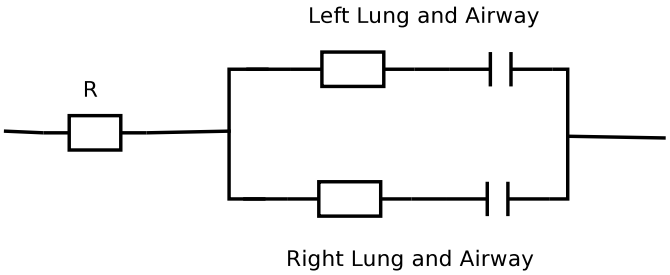


FIGURE 5.4: Extended RC model with two lungs and airways

5.2 Software Patient Simulator

5.2.1 Theory

During development, a simple RC lung model is designed to feasibly testing software subsystems. The simulator, which tries to simulate a real lung and the gas chain, reads the actuator values from the software system and then simulates and returns the sensor values for each breath moment.

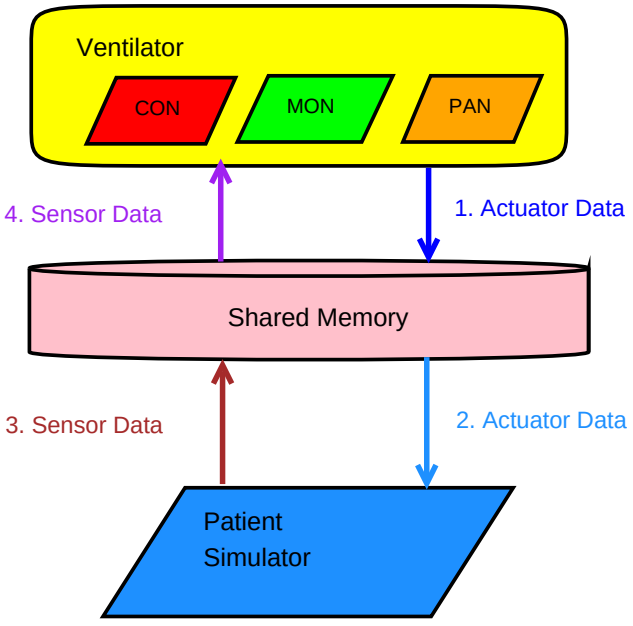


FIGURE 5.5: Patient Simulator on Host

Figure 5.5 illustrates the inter-process communication between the ventilation software system and the patient simulator on host. It's important to note that the ventilator software system is compiled for the host computer architecture as well. We will discuss later that it is a fatal shortcoming of the patient simulator on host.

The patient simulator on host runs in parallel with the ventilator software system. Between the ventilator and the patient simulator, shared memory is introduced to synchronize the gas chain characteristics, including the sensor data and the actuator data, as introduced in the Chapter 2. The patient simulator

1. Read the actuator control signal calculated by the Breath Subsystem;
2. Execute respiratory simulation step as a simple RC lung model;
3. Update the gas chain sensor value to the shared memory, which is observed by the ventilator software system.

On the ventilator side, the software system would think of the shared memory as the ventilator gas chain. Thus, it keeps reading breathing parameters from the shared memory periodically at a fixed high frequency, which is 2000 Hz, just as the same as it works on the target. Then the pre-set mechanical ventilation would be executed to control and monitor the virtual gas chain and controls simulator's respiration.

5.2.2 Limitations and Shortcomings

Despite the patient simulator makes plentiful contributions in development phase, there are several severe limitations and shortcomings.

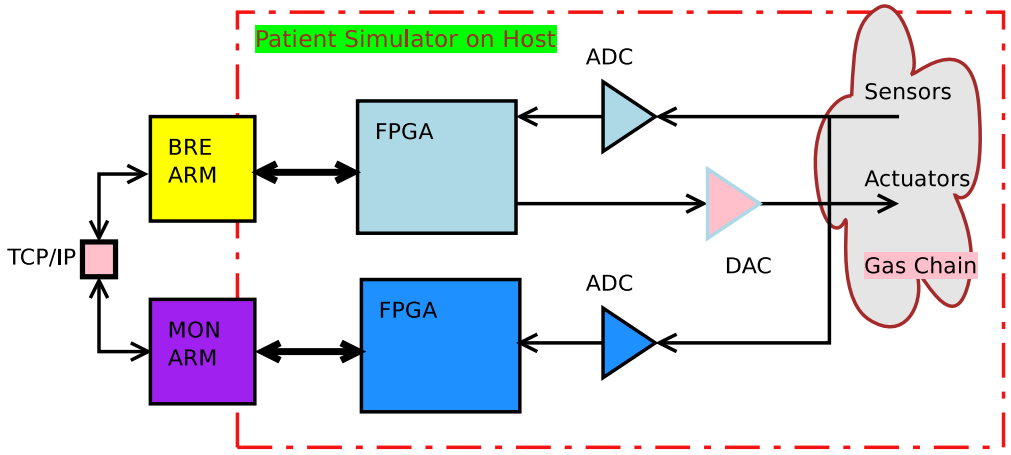


FIGURE 5.6: Ventilator vs PatSim on Host

Figure 5.6 compares the real ventilator with the patient simulator. In ventilator system, FPGA bridges the ventilator software system and the gas chain breathing parameters , which is discussed in previous chapters. When we use patient simulator on host, a software lung model interacts with the ventilator system. It simulates the gas chain characteristics. In the place of FPGA, shared memory is presented to synchronize the

simulator and the ventilator. Therefore the dash line drawn in Figure 5.6 covers all the part which has been abstracted in the patient simulator on host.

Attention should be paid to breathing and monitoring subsystems. Part of the breathing and monitoring is covered by the dash line as well. As mentioned, the ventilator software system communicates with FPGA via an SPI bus while it reads the breathing parameters from virtual shared memory on host. Therefore different software interfaces are utilized for different builds on host and on target. In other words, it's not the exact same software code as the release software and the patient simulator is intrusive to the software system.

What's worse, the critical real timing constraints of the application could not be fulfilled on host. In host testing, the application code would be compiled for and executed on host which is an x86 architecture. At the same time plentiful processes and services run concurrently on host. Unfortunately, RedHat Enterprise Linux, which is the operating system installed on host, does not support real time scheduling. In other words, there is no guarantee that all the timing critical processes could be executed before the deadline expires.

Nevertheless, the application on target would have a definitely different real time behaviour on target. The release application runs on a distributed real-time system and each subsystem runs on an individual arm architecture system. Namely, breathing subsystem runs on the breathing PC board meanwhile monitoring subsystem runs on the monitoring PC board. Embedded Linux with Real Time patch is installed on these PC boards. In additional, the kernel and the root file system is designed and optimized for the PC board.In other words, real-time properties should be tested on target.

There is one more shortcoming. As discussed in Chapter 4, we are trying to figure out test automation to test the system fault tolerance. An efficient way is software implemented fault injection. However, it's still a nice vision today and it's not realized.

To sum up, three severe problems confine the patient simulator on host to development phase. They are:

1. Only partial software code could be tested on host, which means this is an intrusive patient simulator.
2. It's a different build of the application. Real timing constraints could not be fulfilled on host and temporal validity is untestable.
3. Today it's infeasible to inject faults to test system fault tolerance.

Chapter 6

Embedded Patient Simulator

6.1 System Overview

As discussed previously, Maquet ventilator is a distributed real-time system with tight hardware dependencies. Real-time means to export the correct result in time. Thus two aspects should be verified, the output validity and temporal validity. Unfortunately, the tight relation with the hardware components makes it definitely tough for system fault-tolerance evaluation and software system testing. This is due to the fact that it is challenging to simulate hardware fault.

On the other side, a patient simulator on host is introduced based on a simple RC model. The patient simulator, which simulates a human lung and ventilator gas chain, reads the actuator values from the CPU by using the shared memory paradigm and then calculates and returns the sensor values for each breath moment. Nevertheless, it is infeasible to test all the real-time properties and fault-tolerance.

To put thoughts together, a straightforward solution comes up. The main idea is to port the patient simulator to an embedded platform which works as a standalone module that could be connected to the ventilator via a single SPI bus during testing. It reads the actuator reference value from the FPGA block RAM and feedback simulated sensor data through SPI communication. Such that, all the hardware dependencies could be removed and instead, the software system uses the simulated data for control and regulation. Further on, we can play tricks on the simulated data to invoke desired error so that we could realize automated software testing.

Figure 6.1 profiles the embedded patient simulator outline. The embedded platform is Raspberry Pi. Two separate processes run concurrently on Raspberry. One is the patient simulator and the other is the SPI interface. For simplicity, only four type of

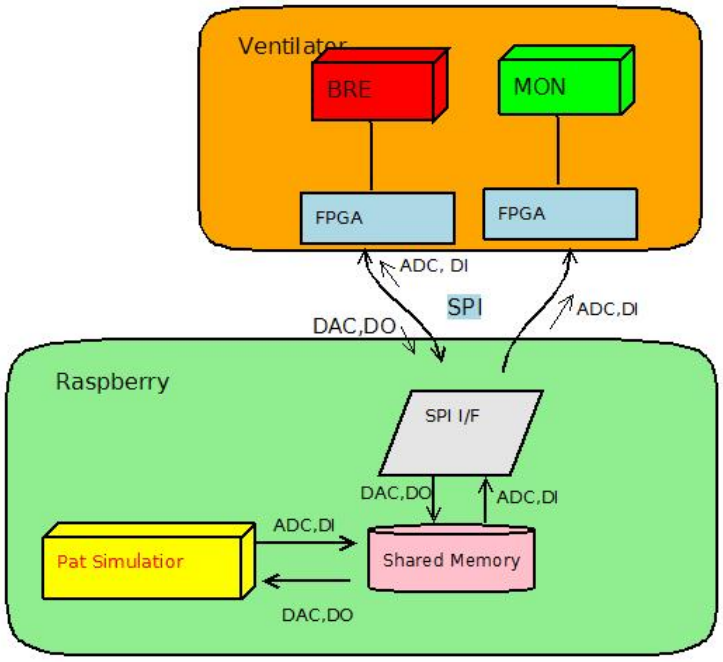


FIGURE 6.1: Patient Simulator on Raspberry
[ADC:Sensor data; DAC: Actuator Reference value; DO: logic output; DI: logic input; BRE: Breathing subsystem; MON: Monitoring subsystem]

data are discussed in this thesis and they are sensor data, actuator value, logic input of ventilators and logic output of ventilators. Patient simulator reads actuator value and digital output from the shared memory on raspberry and feedback simulated sensor data and digital input. The main task of SPI interface is to keep FPGA block RAM and shared memory synchronized. The procedure could be divided into three main tasks as follows:

1. Port the simulator into dedicated embedded platform.
2. FPGA modification on the ventilator and remove hardware dependencies
3. Extend the simulation model to make fault injection possible

6.2 Embedded Patient Simulator

6.2.1 Raspberry and Embedded Linux Development

Raspberry Pi is a credit-card sized, ARM based computer running under GNU Linux. It is one of the most prevalent embedded development board in recent years. The SoC is

a Broadcom BCM2835, containing a ARM6 microprocessor with floating point running at 700 MHz. The Raspberry Pi is proposed for that considering:

- Numerous and well tested Linux ports
- Proven and open source tool GNU chain
- SPI controller and relevant drivers availability
- Open source, popular and inexpensive hardware

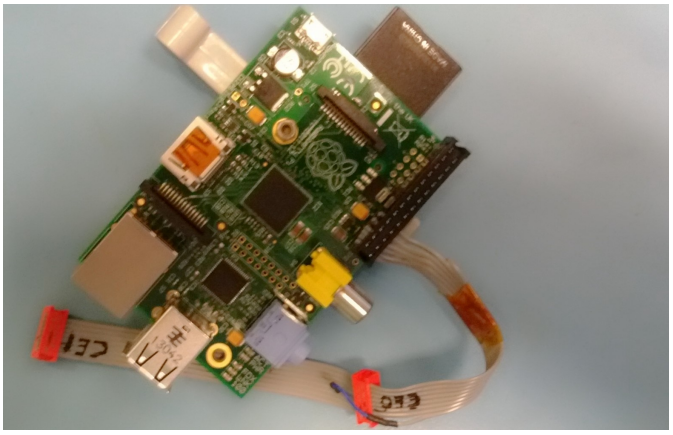


FIGURE 6.2: Raspberry and SPI cable

Diverse Linux distributions have given support to Raspberry Pi, among which is the Arch Linux ARM[27]. Arch Linux ARM is a port of Arch Linux, which arms for simplicity and full control to the end users. Arch Linux ARM provides targeted kernel and root file systems for ARM based development platforms to use their full potential.

A cross compiler is essential to move the development process from the target platform to the Linux x86 host. A cross compiler compiles code and produces binaries that run on a different architecture than where the compiler ran. In Linux, the cross-compiler is frequently referred to as a tool chain because it is a confederation of tools that work together to produce an executable: the compiler, assembler, and linker[28]. The tool chain used in this project is based on the GNU Compiler Collection(GCC) project.

Cross compiling is supported by CMake, which is a cross-platform, open-source make system[29]. CMake generates native makefiles and workspaces that can be used in the compiler environment. However, CMake cannot guess the target system itself, so some CMake variables should be explicitly presented using a tool-chain file. Variables, including CMAKE_SYSTEM_NAME, CMAKE_C_COMPILER, CMAKE_CXX_COMPILER are mandatory. The first variable is the name of the target system and "Linux" and "Windows" are the typical examples. The later two variables point to the C and C++

compiler executable respectively. Additional compiler flags should be modified to suit Raspberry processor architecture.

6.2.2 System Design

Patient Simulator

The patient simulator on the Raspberry is developed from the simulator on host. Considering that the simulation model shall also serve on host during development, the system reserve the same IPC as the simulator on host. The simulator read data from the shared memory and export simulated data to the shared memory. A new process is created to synchronize the shared memory on Raspberry and the FPGA block RAM as shown in Figure 6.1.

As delivered in Section 3.1.2, FPGA samples the breathing parameters at a frequency of 2000 Hz. Thus, a precise patient simulator should run and update the simulated data at 2000 Hz as well, which is a soft real-time task.

Unfortunately, Arch Linux ARM does not support real time scheduling. A software scheduling mechanism is introduced to manage the periodic real time process. Considering the simulation step runs at a high frequency, we can assume that the breathing parameter value(pressure, flow and temperature) will never have a big jump between two contiguous sampling cycles, which means it is acceptable to skip one single cycle.

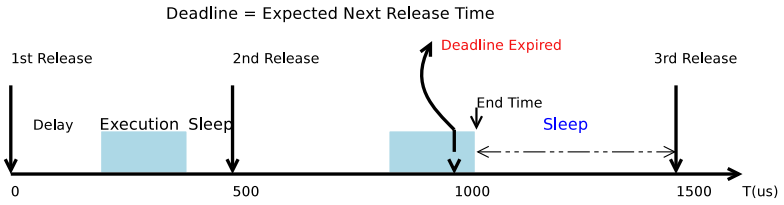


FIGURE 6.3: Software Real Time Scheduling

Figure 6.3 illustrates the basic idea of the software scheduling mechanism. Deadline is equal to the period. In the first cycle, patient simulator finishes the job before the deadline. It is forced to sleep until the next release time point. In the second cycle, patient simulator itself compares the end time with the deadline and unfortunately, deadline has expired already. Instead of releasing immediately, it will skip the third cycle and sleep until the fourth cycle. That's why the third release is at 1500 μs in the figure.

The performance of the software scheduler is directly related to the CPU work load. It is close to strict real time when the work load is light. This is why we would prefer Arch

Linux to Debian Linux. High process priority should be assigned to the process as well to avoid long delays and jitter.

SPI Interface

As discussed, a new process is created to synchronize the patient simulator and the ventilator via SPI bus. It reads data from the shared memory and send to FPGA through SPI after encapsulation. Here Raspberry is the master of the SPI bus and the ventilator subsystems are the slaves. Raspberry configures the SPI bus mode and speed and activates the selected slaves. There are two slaves in this system, which are the breathing and monitoring subsystem. Their update frequency is 2000 Hz and 500 Hz respectively.

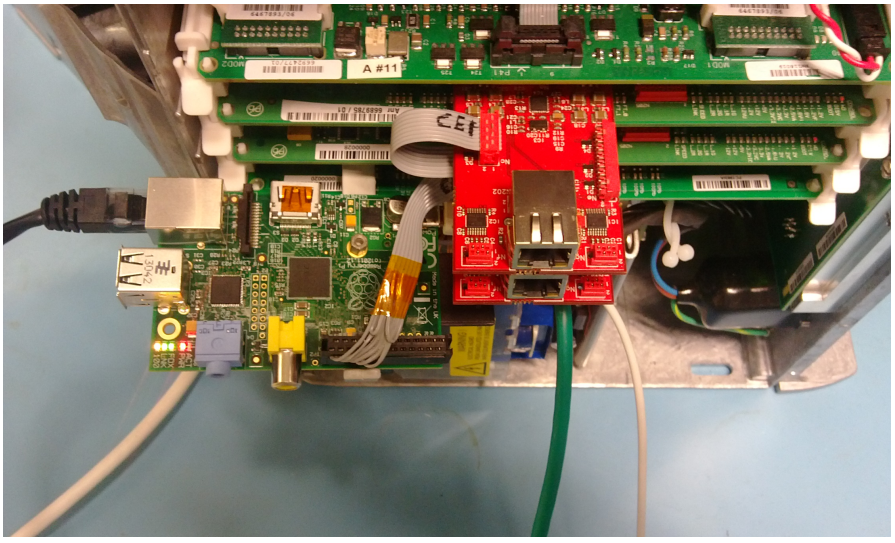


FIGURE 6.4: SPI connection

SPI transmission speed is decided by the clock frequency. A high frequency means a short transmission duration and could help release the CPU load. However, high speed transmission might introduce message error, especially when there is a long bus cable. $12MHz$ is proven to be the optimal option here according to experimental studies.

The SPI message format is uniformed, as shown in Figure 6.5. SCK is not displayed here. It's a clock signal for synchronization, which is configured by patient simulator. The Chip Select (CS) signal indicates when a message begins and ends. The message basic unit is a message frame. All SPI messages contain one or more frames and each frame consists of 32 bits. It will be simplest due to the fact that the shift registers on the CPU and FPGA are 32-bits. The bits are numbered from left to right 31 to 0. Bit 31 is the most significant bit whereas 0 is the least significant bit.

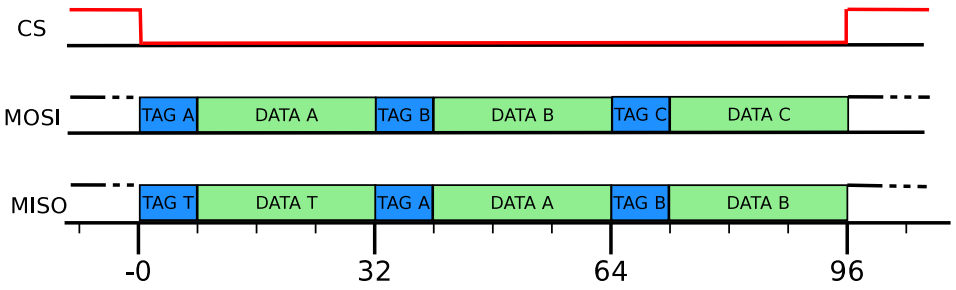


FIGURE 6.5: SPI Message Format

Of the 32 bits, the first byte always comes a tag, which is followed by 24 bits data. Tag is the command identification that tells the FPGA what to execute. The fisrt bit implies to read or to write. Zero means writing to the FPGA whereas one means that the patient simulator reads data from the FPGA. The other seven bits specify what to be written or read.

When the patient simulator starts a transaction, the slave would feed back a time stamp message, tag time and time tickers. The master requests would be responded in the next frame block. If request is write operation, response is the same frame and if it's read operation, FPGA would respond the same tag with the respective data followed. If FPGA sends an unknown tag, it means illegal tag has been received. Illegal tags including undefined tags and no-permission operation.

6.3 Modification on Platform

To recap, software system and FPGA keeps connection via a single SPI bus, referring to Figure 3.2. ALL the breathing parameters used internally in software system are feasted by FPGA rather than the sensors nor actuators directly. In other words, The sensors and actuators are transparent to the software system. Such being the case, the software cannot distinguish between the physically measured data and simulated data. Therefore, it is possible to remove the hardware dependencies and, instead, to use the simulated data for software internal computing. Roughly, we could divided the main task into three steps:

1. *Disconnect ADC/DAC channels and logic PIN/POUT on the FPGA*
2. *Design a specific interface to patient simulator*
3. *Simulation and Testing*

6.3.1 Disconnect Hardware Dependencies

As designed, simulated breathing parameters will update the FPGA block RAM. The ADC channels should be disconnected in case they overwrite the simulated data. Similarly, actuator should be disconnected as well and the patient simulator will observe the actuator reference value and simulate the gas chain.

6.3.2 Implement Interface to Patient Simulator

The patient simulator would be ported to an embedded system(Section 6.2). It communicates with FPGA on an SPI bus and the simulator is the bus master. Thus, here on the FPGA, we should design a SPI slave interface for both breathing and monitoring subsystem. Alongside with the implementation of SPI slave, additional attention should be paid to memory access permission and arbitrator mechanism.

Memory Access Permission: Massive data are stored in the same block RAM. Access permission should be assigned to components to protect the memory from illegal operation. Permission can be classified as read or write. In this case, the new interface should be able to write the breathing parameters and read the actuator reference value.

Memory Arbitrary Mechanism: Multiple access is always accompanied by the problem of collision avoidance. Protocols, like CAN[1] and CSMA/CA[2], are handling of such issues with shared resources. A special arbitrator is introduced at Maquet to taking care of the memory access. The arbitrator will deny the memory access request if the bus is occupied.

6.3.3 Simulation and Testing

To ensure a reliable SPI interface, simulation and testing is mandatory and the most important consideration is the design and creation of effective simulation system and test cases.

Figure 6.6 illustrates the structure of the simulation system. Test bench controller coordinate the functional modules and stimulates the input signals to the FPGA interfaces. All these are simulated in Modelsim SE.

Given constraints on time and cost, the key issue of testing becomes what subset of all possible test cases has the highest probability of detecting the most errors[19]. The following test cases are executed:

[1] Controller Area Network
[2] Carrier Sense Multiple Access with Collision Avoidance

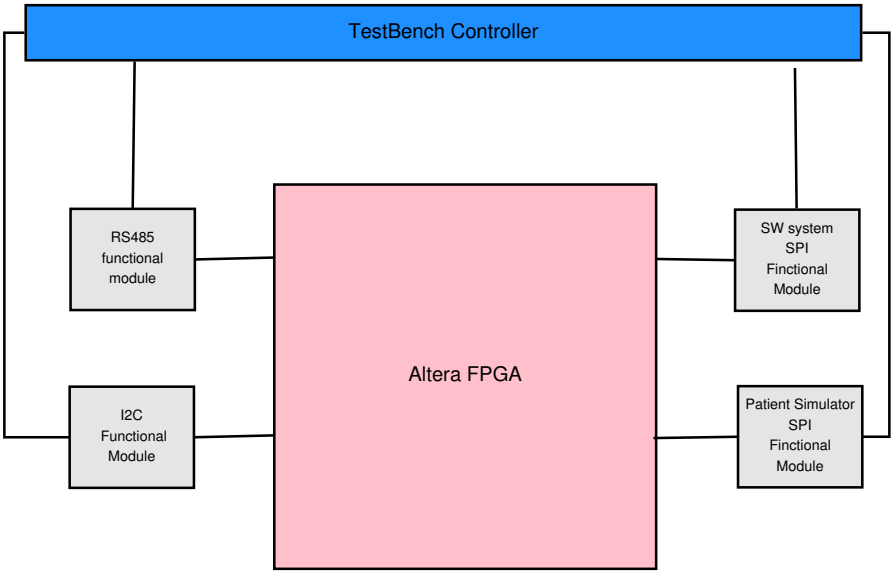


FIGURE 6.6: Testbench

- Patient Simulator writes the ADC channels and software system reads the data
- Software system sets the DAC channels and the Patient Simulator reads data
- Illegal memory access permission testing

After simulation on Modelsim, it should be tested on target and connected to the Raspbery. A simple SPI testing application is designed to write or read arbitrary data through SPI on the Raspberry side. Python Unit-test is applied to have full control on the test cases.

6.4 Software Implemented Fault Injection

Fault injection is implemented in a server/client mode as shown in Figure 6.7. The host Linux is the client computer. The client is a user friendly Python script and fault injection request could be initiated by a single command line. The server runs on the Raspberry and it is a thread of the patient simulator process so that the simulator on host would be capable to inject fault as well. In-between is the Google protocol buffer which carries the request message.

6.4.1 Client and Request Message

The client is a Python script on host. Fault injection request is encapsulated in a Google protocol buffer message(Chapter 3.2.2. Table 6.1 lists all the fields of the protocol buffer.

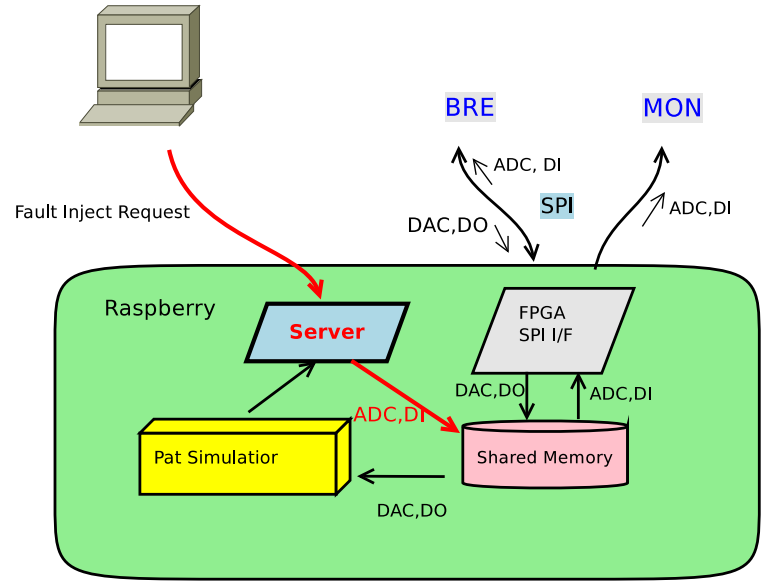


FIGURE 6.7: Fault Injection on Raspberry

Tag	Field	Rules	Options
1	Request type	Required	Inject/Remove
2	Target Subsystem	Required	Bre/Mon
3	Fault Signal	Required	Unique Channel Number
4	Error Type	Optional	Constant/Percent error
5	Error Value	Optional	Integer

TABLE 6.1: Fault Inject Request Message

Request Type: Fault injection is to force the occurrence of the desired faults. But it should also be able to remove the injected fault.

Target Subsystems: There are two subsystems that observe the breathing parameters and logic signals. The request message should specify where the fault arises.

Faults Signal: With no doubt, you should tell the server which breathing parameter or logic signal is infected. Unique ID is assigned to all the channels.

Error Type: There are various kinds of error, such as offset value, additional noise. Here we implement two types: constant value or percentage error. It is sufficient so far for software testing. Advanced error type could be added when necessary. Error type is an optional field. It is not required when to remove faults.

Error value: If it is a percentage error, the valid value ranges from -100 to 100. When it is of constant error, the error value could arbitrary number between 0 and 65535.

6.4.2 Server

The server is the fault injection manager. Four maps are created to manage the faults. There is a error information map and a data address map for breathing subsystem and the same for monitoring subsystem.

Error information maps are dynamic maps. They are empty after initiation and items would be inserted/removed when request is received. The signal unique ID is the key and it is mapped to a predefined structure including all the essential error information, including target subsystem, error type and error value.

Data address maps are static maps. They are initiated at beginning. Same as the error information maps, signal unique ID is the map key. The mapped value is the memory address which corresponds to the signal.

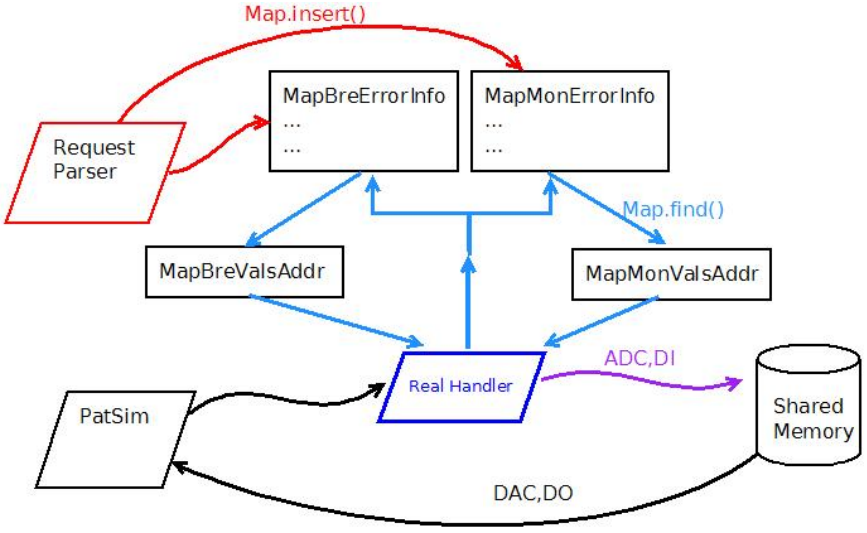


FIGURE 6.8: Fault Injection Server

Figure 6.8 highlights the main processes in fault injection. Once a new request is received, the server would parse the message and insert/remove items to/from the error information maps. In each simulation step cycle, the real handler would query the error information maps to check if there is any fault injection request. If not, the simulated data is copied to the shared memory. If yes, go to data address maps, find the corresponding memory address with the same key and modify the data value in the memory space. This is how we inject faults.

6.5 Summary

The embedded patient simulator consists of two significant processes. One is the simulation model that tries to simulate a human lung and the ventilator gas chain. The simulator reads actuator value from the shared memory and feedback simulated sensor data. The faults are injected before the simulated data are exported to the shared memory.

The other process is the SPI interface which synchronizes the shared memory and the FPGA block RAM. Only four types of data are discussed in the thesis for simplicity. The SPI interface process communicates with both breathing and monitoring subsystem.

Comparing the release ventilator and testing setup, as shown in Figure 6.9, the sole difference is that the gas chain is replaced by the embedded patient simulator. As we discussed, the gas chain is transparent to the software system so that we say this is non-intrusive patient simulator. The embedded patient simulator interacts with the software system on target so that all the real-time properties could be tested. What's more, fault injection is implemented and all the simulated data could invoke error.

To sum up, the embedded patient simulator has removed the hardware dependencies and all the hardware fault could be simulated and injected in a software way.

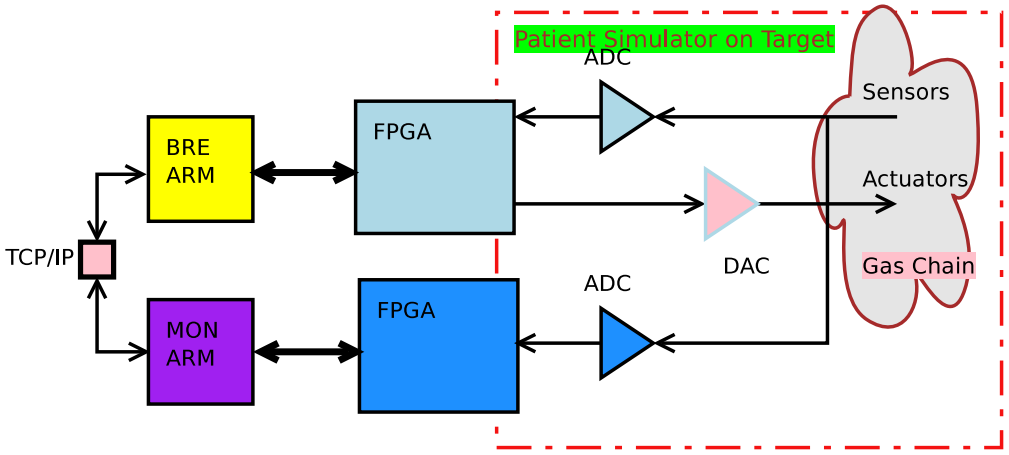


FIGURE 6.9: Embedded Patient Simulator v.s. Ventilator

FIGURE 6.10: Patient Simulator and Ventilator

Chapter 7

Experiment and Conclusion

7.1 Integrate with AVA

AVA is a test framework that simplifies and unifies the procedure of writing advanced system and subsystem tests. The purpose of AVA is to allow for automated regression testing, reduce maintenance work, and to help test writers to understand each other's test code.

AVA is written in Python and runs primarily on Linux systems, mainly because the original test targets (BRE/MON/PAN) are built as Linux ELF binaries. AVA uses the Python unit-test framework for its test cases. The unit-test framework gives deep control of the test flow, and provides functions for separating test methods, setup code before each test method, tear-down code after each test method, pre-test setup code, etcetera.

A test case is a collection of test methods needed to test a specific requirement. The test method setup is predefined in unit-test and is used to test various aspects of for example a requirement. A test case may contain one or several test methods. When a test case is executed, AVA will run all test methods defined in the test case, gather statistics and present a result for the test case.

7.2 Experiment Setup

Figure 7.1 highlights the connections between different parts of the test system. The host, the embedded patient simulator and the ventilator are all on the Ethernet. Meanwhile, the patient simulator can communicate with the breathing and monitoring subsystems via a single SPI bus. Testers could start test cases on the host and the AVA system would take care of the test methods.

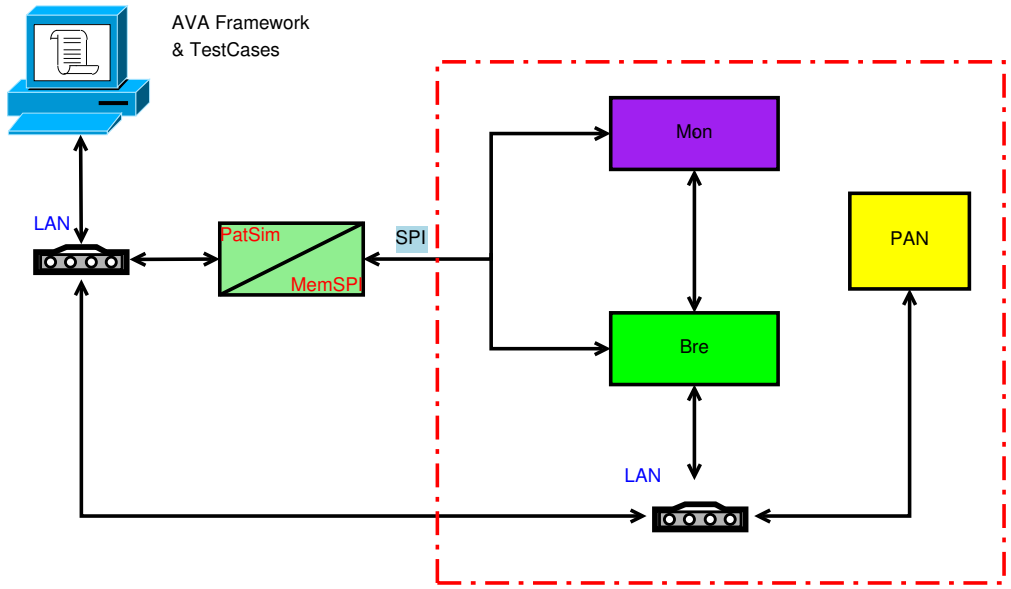


FIGURE 7.1: Experiment Setup

7.3 Experiment and Evaluation

Here we will compare the difference between manual testing and automated testing. The example is to verify the barometric pressure alarm.

7.3.1 Example Test Case

To verify that a barometric pressure too low($BARO_PRESS_TOO_LOW$) alarm shall be triggered if the measured barometric pressure is below (650±10) hPa and that a barometric pressure too high($BARO_PRESS_TOO_HIGH$) alarm shall be triggered if the measured barometric pressure is higher than (1070±10) hPa and if the alarm is activated, the barometer pressure used internally in the Monitoring Subsystem shall be limited to 650/1070 hPa if a lower/higher pressure is detected. It also verifies that the alarm has the correct error code.

7.3.2 Manual Testing vs Automated Testing

In conventional testing stage, manual manoeuvres is required due to the hardware dependencies. The test case of the $BARO_PRESS_TOO_LOW$ alarm is listed as follows:

1. Simulate a barometric pressure of 660 hPa(Apply a voltage that corresponds to a barometric pressure of 660 hPa at a specified pin);
2. Verify that no error message is activated regarding barometric pressure;

3. Simulate a barometric pressure of 640 hPa and verify that a technical "Barometric sensor error" alarm with high priority and correct code is activated;
4. Verify that the barometer pressure used internally in the Monitoring Subsystem is limited to 650 hPa if a lower pressure is detected;
5. Simulate a barometer pressure above 660 hPa and verify that the alarm is still active.
6. Restart the system and verify that the alarm is deactivated.

As we can see, testers need to apply a certain voltage to simulate the barometer error at Step 1 and 3. The manual job is of low efficiency and it is error prone.

The presence of embedded patient simulator resolves the hardware dependencies and it could simulate gas chain. To test under failure mode, faults could be injected from the host side. Here we will give the pseudo code instead of the entire Python unittest case.

```
{//AVA Setup Method
        //Set up the Patient Simulator
        StartPatientSimulator(); //SSH command
        ConfigurePatientSimulator(); //Protocol Buffer Message
        StartSPIInterface(); //SSH command

        //StartVentilator
        StartSoftwareSystem(); // SSH command
        ConfigurePatientCategory(); // Squish
        ConfigureVentilationMode(); // Squish
        StartVentilation();     // Squish
}

{//Unit Test Case
        //Play Magic Here
        //Correspond to Step 1 and 2 in Manual Testing
        InjectFault(Barometer,660hPa); // Protocol Buffer Message
        assertfalse(BarometerError); // AVA_API

        //Step 3 in Manual Testing
        InjectFault(Barometer,640hPa);
        assertTrue(BarometerError);
        assertTrue(BarometerPressureTooLow);

        //Step 4 in Manual Testing
        CheckInternalBarometerValue(); //AVA API
```

```
            //Step 5 in Manual Testing
            InjectFault(Barometer,660hPa);
            assertTrue(BarometerError);
            assertTrue(BarometerPressureTooLow);

            //Step 6 in Manual Testing
            RebootVentilator(); // SSH command
            assertfalse(BarometerError);
    }

    {//AVA teardown method
            RemoveAllFaults(); //Protocol Buffer
    }
```

7.4 Comparison and Conclusion

In conventional testing, manual manoeuvres is mandatory due to the tight hardware dependencies. If there is only a small number of test cases, manual testing is acceptable. It requires little time and expense to begin productive manual testing and short term costs are reduced.

However, manual testing could be very time consuming when there are plentiful test cases. Here we just give one single test case. However, it is only the tip of the iceberg and there are a vast amount of test cases which require manual manoeuvres. Considering the fact that you must rerun the same set of test cases for each single release, it is tiresome.

What's worse, it is error prone. Taking the first step as an example, the integrated circuit is of great complexity and the pins are intensively crowded together. Testers might apply the voltage to a wrong pin. Various faults might be introduced by manual job. Therefore, the quality of manual testing is not guaranteed.

The presence of the embedded patient simulator makes test automation possible, which is a momentous step for verification methodologies at Maquet.

The embedded patient simulator works as a standalone module during software testing. the gas chain dependency is removed and instead, the simulator is interfaced with the ventilator. The simulator reads the actuator reference values and returns sensor value for each breath moment. The ventilator software system runs on target which means that all the real-time properties of the distributed real-time system could be tested.

Furthermore, hardware faults could be simulated and injected on the patient simulator, which is transparent to the software system. Thus, it is of non-intrusive implementation.

Last but not the least, test scripts using the embedded patient simulator could be integrated with AVA framework, which is aimed for automated regression testing. In other words, it is promising to realise entirely automated testing in the near future.

Chapter 8

Future Work

As we conclude in Chapter 7, the embedded patient simulator, which is presented in this thesis, resolves the tight hardware dependencies and realises software-implemented fault injection. This is a non-intrusive patient simulator and all the real-time properties could be tested on target. It is a significant step to test automation. However, there are several aspects need further studies or to be improved in the future work.

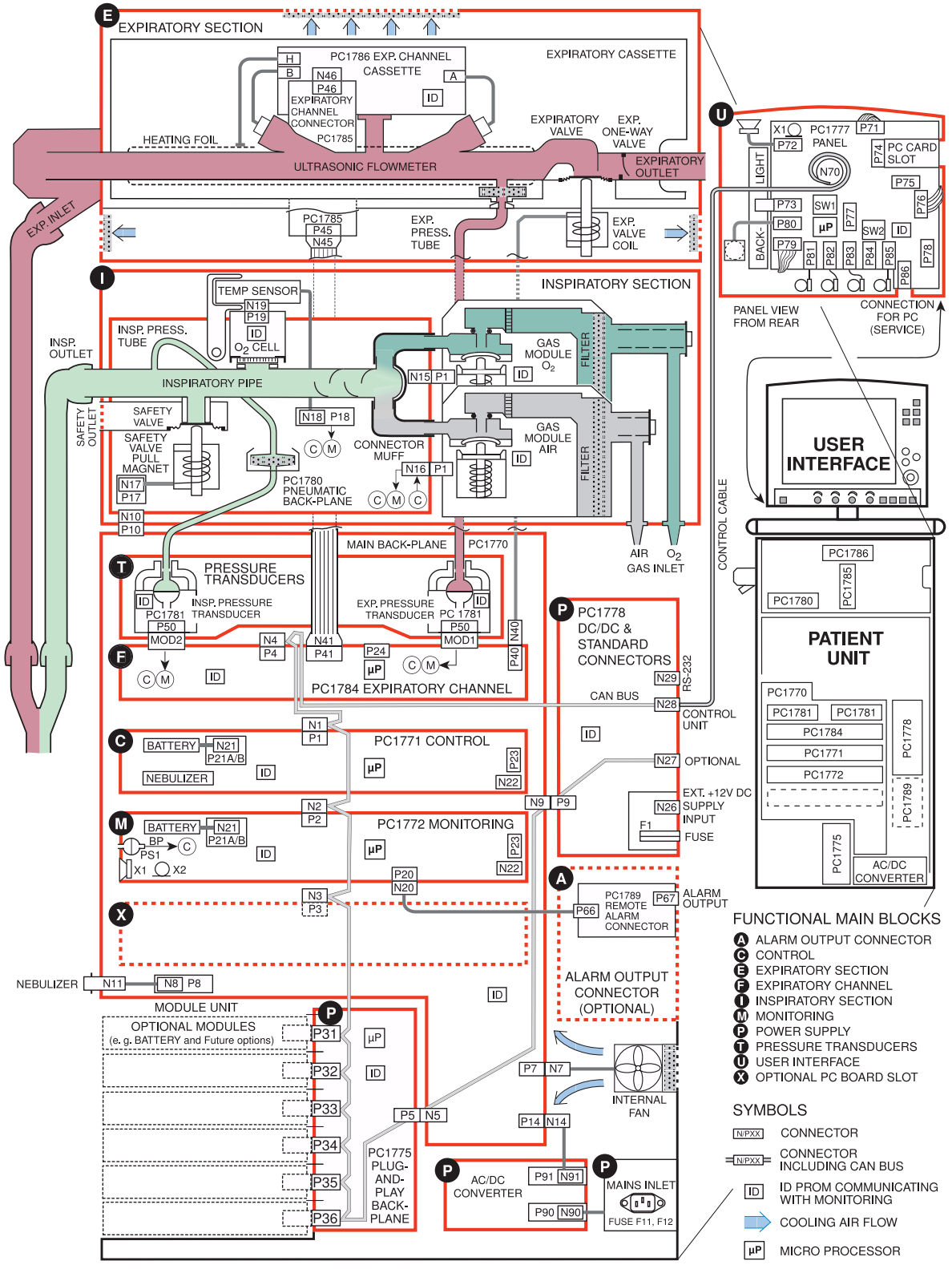
- *Advanced Lung Model and Patient Simulator* The lung model used here is a simple RC model. As discussed in Section 5.1, the simple RC model could be extended to a non-linear model to get a better lung behaviour description to the reality. What's more, weak breathe attempts could be added as new features.
- *High Performance Embedded Hardware* Considering the fact that Arch Linux Arm does not support real time scheduling, a software scheduling method is introduced. However, the implementation is not strict real-time and the performance is affected by the CPU work load. A more powerful embedded hardware is essential to satisfy the timing constraints. If possible, real time patch is appreciated for the embedded Linux.
- *Test Scripts Design and Maintenance* Proficiency is required to design and debug the automated test scripts. If any error present in the test scripts, it may lead to deadly consequences.

Appendix A

SERVO-i Diagram

See next page.[1]

[1]Diagram Source: ref. [8] User Manual SERVO-i VENTILATOR SYSTEM V6


E
EXPIRATORY SECTION
PC1786 EXP. CHANNEL CASSETTE
EXPIRATORY CASSETTE
H
B
N46
P46
EXPIRATORY CHANNEL CONNECTOR
PC1785
A
ID
HEATING FOIL
EXPIRATORY VALVE
EXP. ONE-WAY VALVE
ULTRASONIC FLOWMETER
EXPIRATORY OUTLET
EXP. INLET
PC1785
P45
N45
EXP. PRESS. TUBE
EXP. VALVE COIL
I
INSPIRATORY SECTION
TEMP SENSOR
N19
P19
ID
O2 CELL
INSP. PRESS. TUBE
INSP. OUTLET
GAS MODULE O2
FILTER
N15
P1
INSPIRATORY PIPE
SAFETY OUTLET
SAFETY VALVE
SAFETY VALVE PULL MAGNET
N17
P17
N18
P18
C
M
CONNECTOR MUFF
GAS MODULE AIR
N16
P1
PC1780 PNEUMATIC BACK-PLANE
N10
P10
AIR
O2
GAS INLET
T
PRESSURE TRANSDUCERS
MAIN BACK-PLANE
PC1770
ID
PC1781
INSP. PRESSURE TRANSDUCER
EXP. PRESSURE TRANSDUCER
P50
MOD2
MOD1
N4
P4
N41
P41
P24
μP
N40
P40
F
PC1784 EXPIRATORY CHANNEL
P
PC1778 DC/DC & STANDARD CONNECTORS
N29
RS-232
CAN BUS
N28
CONTROL UNIT
C
BATTERY
N21
P21A/B
NEBULIZER
N1
P1
PC1771 CONTROL
P23
N22
N27
OPTIONAL
M
BP
PS1
X1
X2
N2
P2
PC1772 MONITORING
N9
P9
N26
EXT. +12V DC SUPPLY INPUT
F1
FUSE
A
PC1789 REMOTE ALARM CONNECTOR
P67
P66
ALARM OUTPUT
X
P20
N20
N3
P3
ALARM OUTPUT CONNECTOR (OPTIONAL)
NEBULIZER
N11
N8
P8
MODULE UNIT
OPTIONAL MODULES
(e. g. BATTERY and Future options)
P31
P32
P33
P34
P35
P36
PC1775 PLUG-AND-PLAY BACK-PLANE
P7
N7
INTERNAL FAN
P5
N5
P14
N14
AC/DC CONVERTER
P91
N91
P90
N90
MAINS INLET
FUSE F11, F12
U
X1
PC1777 PANEL
P71
P72
P74
PC CARD SLOT
LIGHT
N70
P75
P73
SW1
P77
P76
P80
μP
SW2
ID
BACK-
P79
P81
P82
P83
P84
P85
P86
P78
PANEL VIEW FROM REAR
CONNECTION FOR PC (SERVICE)
CONTROL CABLE
USER INTERFACE
PC1786
PC1785
PC1780
PATIENT UNIT
PC1770
PC1781
PC1781
PC1784
PC1771
PC1772
PC1778
PC1789
PC1775
AC/DC CONVERTER
FUNCTIONAL MAIN BLOCKS
A ALARM OUTPUT CONNECTOR
C CONTROL
E EXPIRATORY SECTION
F EXPIRATORY CHANNEL
I INSPIRATORY SECTION
M MONITORING
P POWER SUPPLY
T PRESSURE TRANSDUCERS
U USER INTERFACE
X OPTIONAL PC BOARD SLOT
SYMBOLS
N/PXX CONNECTOR
N/PXX CONNECTOR INCLUDING CAN BUS
ID ID PROM COMMUNICATING WITH MONITORING
COOLING AIR FLOW
μP MICRO PROCESSOR

Appendix B

Example Test Case

Barometer Pressure too Low/High Alarm

Application Lifecycle Management Test ID:8601

Purpose

To verify that a Baro_Press_Too_Low(with high priority, mutable and latchable) alarm shall be triggered if the measured barometric pressure is below (650±10) hPa and that a Baro_Press_Too_High(with high priority, mutable and latchable) alarm shall be triggered if the measured barometric pressure is higher than (1070±10) hPa and the barometer pressure used internally in the Monitoring Subsystem shall be limited to 650/1070hPa if a lower/higher pressure is detected. It also verifies that the alarm has the correct error code.

Also to test that the Baro_Press_Too_Low and Baro_Press_Too_High alarm shall be deactivated at restart only and that the barometer pressure is updated every third second.

The purpose is also to test that the Barometric Pressure used for calibration or linearization shall not be outside the range (650-1070) $mbar$. If a value outside this range is measured, the limit shall be used in calculations.

Test Design

For one optional patient category and ventilation mode do the following:

1. Simulate a barometric pressure of 660 hPa(Apply a voltage that corresponds to a barometric pressure of 660 hPa between point R102/C44 and ground).
2. Verify that no error message is activated regarding low barometric pressure.
3. Simulate a barometric pressure above 660 hPa and verify that the barometer pressure is updated at least every third second.
4. Simulate a barometric pressure of 640 hPa and verify that a Technical "Barometric sensor error" alarm with high priority and correct error code is activated.
5. Verify that the barometric pressure used internally in the monitoring system is limited to 650 hPa if a lower pressure is detected.
6. Simulate a barometer above 660 hPa and verify that the alarm is still active.
7. Press mute button and verify that the alarm is mutable
8. Restart system and verify that the alarm is deactivated.
9. Simulate a barometric pressure of 1070 hPa and verify that no error message is activated regarding high barometric pressure.
10. Simulate that a barometric pressure of 1070 hPa and verify that a technical "Barometer sensor error" alarm with high priority and correct error code is activated.
11. Verify that the barometric pressure used internally in the Monitoring Subsystem is limited to 1070 hPa if a higher pressure is detected.
12. Simulate a barometric pressure and verify that the alarm is still active.
13. Press mute button and verify that the alarm is mutable.
14. Restart the system and verify that the alarm is deactivated.
15. Start ventilating in adult patient category in VC mode(with high Tidal Volume)
16. Simulate a barometric pressure of 650 hPa and document the value of Inspiratory Tidal Volume(VTi).
17. Adjust the voltage to simulate a barometer pressure below 650 hPa and verify that the VTi is not changed(the same value as in step 16).
18. Restart the ventilator to deactivate the alarm.
19. Simulate a barometric pressure of 1070 hPa and document the value of VTi.
20. Adjust the voltage to simulate a barometer pressure above 1070 hPa and verify that the VTi is not changed(the same value as in step 19).

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